86-771

No.

Supreme Court, U.S.
FILED
NOV 12 1986
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

INTERMEDICS INC.,

Petitioner,

v.

MEDTRONIC, INC. and MEDTRONIC PUERTO RICO, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ROY E. HOFER
One IBM Plaza, Suite 4100
Chicago, Illinois 60611
(312) 822-9800
Attorney for Petitioner

Of Counsel:
WANNELL M. CROOK
HAROLD V. JOHNSON
WILLIAN BRINKS OLDS HOFER GILSON & LIONE LTD.

Midwest Law Printing Co., Chicago 60611, (312) 321-0220

5100

QUESTIONS PRESENTED

In the jury trial of a federal civil case:

1. Is it prejudicial error for the trial court to exclude relevant, noncumulative testimony of an admittedly qualified expert when the expert had, pursuant to Fed. R. Evid. 703, formed his opinions upon facts and data made known to him before the hearing?

2. Where the trial court does not rely upon Fed. R. Evid. 403 to exclude relevant expert testimony, may the appellate court conduct the balancing required by Rule 403?

3. When relevant expert testimony is erroneously excluded, what standard should the appellate courts use to determine whether the error was harmless or prejudicial?

STATEMENT PURSUANT TO RULE 28.1

Petitioner Intermedics Inc. does not stand in the position of parent, affiliate or subsidiary to any other corporation.

TABLE OF CONTENTS

	PAGE
QUESTIONS PRESENTED	i
STATEMENT PURSUANT TO RULE 28.1	ii
TABLE OF CONTENTS	iii
INDEX TO THE APPENDIX	iv
TABLE OF AUTHORITIES	v
TABLE OF ABBREVIATIONS	viii
OPINIONS BELOW	1
JURISDICTION	2
STATUTORY PROVISIONS INVOLVED	2
STATEMENT OF THE CASE	2
REASONS FOR GRANTING THE WRIT	5
I.	
THE EXCLUSION OF MR. GAMBRELL'S TESTIMONY WAS MANIFEST ERROR UNDER RULE 703	7
II.	
THE CAFC IGNORED RULE 403 AND THUS MADE A FLAWED ANALYSIS OF HARMLESS/PREJUDICIAL ERROR	8
III.	
THE ERRONEOUS EXCLUSION OF MR. GAMBRELL'S TESTIMONY WAS PREJUDICIAL ERROR	10
A. The Circuit Courts Have Used Conflicting Standards To Determine Harmless/Prejudicial Error	10

B. Without Doubt The Exclusion Of Mr. Gambrell's Testimony Was Prejudicial Error 13

CONCLUSION 16

INDEX TO THE APPENDIX

	PAGE
Opinion of the Court of Appeals, August 15, 1986 .	A 1
Amended Judgment of the District Court	A 17
28 U.S.C. § 2111	A 19
Federal Rule of Evidence 103	A 19
Federal Rule of Evidence 402	A 20
Federal Rule of Evidence 403	A 20
Federal Rule of Evidence 703	A 20
Federal Rule of Civil Procedure 61	A 20
Intermedics' Offer of Proof	A 21

TABLE OF AUTHORITIES

Cases	PAGE
Barefoot v. Estelle, 463 U.S. 880 (1983)	7
Blonder-Tongue Laboratories, Inc. v. University of Illinois Found., 402 U.S. 313 (1971)	5
Brooks v. Chrysler Corp., 786 F.2d 1191 (D.C. Cir.), *cert. denied*, 55 U.S.L.W. 3235 (1986)	8
Collum v. Butler, 421 F.2d 1257 (7th Cir. 1970) ..	12
Contemporary Mission, Inc. v. Famous Music Corp., 557 F.2d 918 (2d Cir. 1977)	8, 9
Cook v. Spencer, 688 F.2d 1017 (5th Cir. 1982) ..	8
DMI, Inc. v. Deere & Co., 231 USPQ 276 (Fed. Cir. 1986)	13
Dartez v. Fibreboard Corp., 765 F.2d 456 (5th Cir. 1985)	11
Dixon v. International Harvester, 754 F.2d 573 (4th Cir. 1985)	7
E.F. Hutton & Co. v. Berns, 682 F.2d 173 (8th Cir. 1982)	11
E.I. du Pont de Nemours v. Berkley & Co., 620 F.2d 1247 (8th Cir. 1980)	11
Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565 (Fed. Cir. 1983)	10, 14
Goldberg v. Medtronic, Inc., 209 USPQ 259 (N.D. Ill. 1980), *aff'd*, 686 F.2d 1219 (7th Cir. 1982) .	15
Haddad v. Lockheed California Corp., 720 F.2d 1454 (9th Cir. 1983)	11

Harpring v. Continental Oil Co., 628 F.2d 406 (6th Cir. 1980), *cert. denied*, 454 U.S. 819 (1981) ... 9

In re Japanese Elec. Prods. Antitrust Litig., 723 F.2d 238 (3d Cir. 1983) 7

International Bureau, Inc. v. Bethlehem Steel Co., 192 F.2d 304 (2d Cir. 1951) 12

International Merger & Acquisition Consultants, Inc. v. Armac Enters., Inc., 531 F.2d 821 (7th Cir. 1976) 12

Johnson v. William C. Ellis & Sons Iron Works, Inc., 604 F.2d 950 (5th Cir. 1980), *modified on other grounds*, 609 F.2d 820 (5th Cir. 1980) .. 12

Kori Corp. v. Wilco Marsh Buggies and Draglines, Inc., 561 F. Supp. 512 (E.D. La. 1981), *aff'd*, 708 F.2d 151 (5th Cir. 1983), *transferred and aff'd*, 761 F.2d 649 (Fed. Cir.), *cert. denied*, 106 S. Ct. 230 (1985) 15

Lovett v. Shuster, 633 F.2d 98 (8th Cir. 1980) ... 11

Mannino v. International Mfg. Co., 650 F.2d 846 (6th Cir. 1981) 7

McIlroy v. Dittmer, 732 F.2d 98 (8th Cir. 1984) .. 11

McQueeney v. Wilmington Trust Co., 779 F.2d 916 (3d Cir. 1985) 11

Medtronic, Inc. v. Catalyst Research Corp., 547 F. Supp. 401 (D. Minn. 1982) 15

Memphis Community School Dist. v. Stachura, 54 U.S.L.W. 4771 (1986) 15

Miller v. Poretsky, 595 F.2d 780 (D.C. Cir. 1978) . 9, 12

Moeller v. Ionetics, Inc., 794 F.2d 653 (Fed. Cir. 1986) 2, 10, 14

O'Rear v. Fruehauf Corp., 554 F.2d 1304 (5th Cir. 1977) 11, 12

Panduit Corp. v. All States Plastic Mfg. Co., 744 F.2d 1564 (Fed. Cir. 1984) 13

Perry v. Larson, 794 F.2d 279 (7th Cir. 1986) ... 12

Pregeant v. Pan American World Airways, Inc., 762 F.2d 1245 (5th Cir. 1985) 11

Ramsey v. Culpepper, 738 F.2d 1092 (10th Cir. 1984) 7

Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832 (2d Cir. 1967) 12

Rosebud Sioux Tribe v. A & P Steel, Inc., 733 F.2d 509 (8th Cir.), *cert. denied*, 105 S. Ct. 565 (1984) . 11

Salem v. United States Lines Co., 370 U.S. 31 (1962) 7

Shad v. Dean Witter Reynolds, Inc., 799 F.2d 525 (9th Cir. 1986) 14

Sims Consol., Ltd. v. Irrigation and Power Equip., Inc., 518 F.2d 413 (10th Cir.), *cert. denied*, 423 U.S. 913 (1975) 12

U.S. Indus., Inc. v. Norton Co., 578 F. Supp. 1561 (N.D.N.Y. 1984) 15

United States v. Burke, 781 F.2d 1234 (7th Cir. 1983) 9

United States v. Downing, 753 F.2d 1224 (3d Cir. 1985) 9

United States v. Layton, 720 F.2d 548 (9th Cir. 1983), *cert. denied*, 465 U.S. 1069 (1984) ... 9

United States v. Lebovitz, 669 F.2d 894 (3d Cir.), *cert. denied*, 456 U.S. 929 (1982) 8

United States v. Schwartz, 790 F.2d 1059 (3d Cir. 1986) 9

Other Authorities

28 U.S.C. § 2111 ..... 1, 6, 10

Federal Rule of Evidence 103 ..... 1, 6, 10

Federal Rule of Evidence 402 ..... 1, 8

Federal Rule of Evidence 403 ..... 1, 5, 6, 8-10, 14

Federal Rule of Evidence 703 ..... 1, 5-8

Federal Rule of Civil Procedure 61 ..... 1, 6, 10

Rossi, *Modern Evidence and the Expert Witness*, 12 A.B.A.J. Sec. Lit. 18 (Fall 1985) 5

R. Traynor, *The Riddle of Harmless Error* (1970) 6, 12, 14

TABLE OF ABBREVIATIONS

A ..... Appendix

JA ..... Joint Appendix Filed In CAFC

MB ..... Medtronic's Brief On Appeal

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

INTERMEDICS INC.,

Petitioner,

v.

MEDTRONIC, INC. and
MEDTRONIC PUERTO RICO, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit (CAFC) is reported at 799 F.2d 734, 230 USPQ 641, and is reprinted in the Appendix hereto at A 1. The Amended Judgment of the United States District Court for the Southern District of Texas, entered on October 10, 1985, is at A 17.

JURISDICTION

The final judgment of the CAFC was entered on August 15, 1986. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Title 28, United States Code § 2111; Federal Rules of Evidence 103, 402, 403 and 703; and Federal Rule of Civil Procedure 61. These are reproduced at A 19.

STATEMENT OF THE CASE

Respondents Medtronic, Inc. and Medtronic Puerto Rico, Inc. (collectively "Medtronic") sued Intermedics under 28 U.S.C. § 1338 for infringement of U.S. Patent No. 3,927,510 (the C/D patent). Intermedics counterclaimed for infringement of U.S. Reissue Patent No. 30,366 (the R/S patent).

At issue were the validity (a mixed fact/law question) and infringement (a fact question) of the R/S patent. To properly resolve these issues, the trier of fact must analyze the proceedings in the United States Patent and Trademark Office (PTO) that resulted in the issuance of this patent, e.g., what was said to and by the PTO as the applicants sought their patent. *Moeller v. Ionetics, Inc.*, 794 F.2d 653, 656 (Fed. Cir. 1986). These proceedings are recorded in a file called the prosecution (or file) history.

Only experienced patent lawyers have sufficient knowledge of PTO procedures to understand and explain the significance of the prosecution history upon validity and infringement issues. Therefore, it is commonplace in patent cases, whether bench or jury trials, to have patent lawyers testify on validity or infringement issues, or both (JA 130.1).

Thus, in the Pretrial Order, both Intermedics and Medtronic had distinguished patent lawyers on their Witness List, James Gambrell and Donald Banner, respectively. Although neither had participated in the prosecution of the R/S patent, both were listed by the parties to "testify concerning the prosecution of" the R/S patent (JA 38).

The case was tried before a jury in Galveston, Texas. During opening statements Medtronic's counsel told the jury:

> Mr. Banner will testify concerning the ongoing activities in the Patent Office and give you an insight into these two patents . . . . *He will interpret for you what went on*, because like in every other administrative proceeding, the jargon begins to take over and the paper, sometimes the paper begins to proliferate. [JA 141-42] [Emphasis added.]

During its case Intermedics offered, and the district court accepted, Mr. Gambrell as a patent expert (JA 1695). Mr. Gambrell had reviewed the prosecution history of the R/S patent and was prepared to testify about the effect of the prosecution history on the validity and infringement issues (A 21-24). However, the district court ruled that Mr. Gambrell could not testify about the R/S patent, because he had not participated in, and therefore did not have first-hand knowledge of, the prosecution of the patent (A 21, 24-25). Thus the district court confined Mr. Gambrell's testimony to basic patent law principles (JA 1688-1721).

After Medtronic successfully precluded Mr. Gambrell's testimony, it did not call Mr. Banner, despite having told the jury he would "interpret for you what went on" in the PTO. No witness testified about the prosecution history of the R/S patent and its effect upon the issues.

Specifically, Mr. Gambrell would have testified about the following subjects relating to the R/S patent: the claimed invention; its prosecution history; the effect of its prosecution history upon the scope of the asserted claims; the nonobviousness of the asserted claims in view of the prosecution history; and whether Medtronic's commercial products infringed the asserted claims. See Intermedics' extensive offer of proof, reproduced at A 21-25.

It is undisputed that such testimony would have been relevant to the issues decided by the jury.

Without this relevant evidence, the jury found the R/S patent invalid and not infringed by Medtronic. Intermedics moved, *inter alia*, for a new trial on the issues of the validity and infringement of the R/S patent based on the exclusion of Mr. Gambrell's testimony.

The district court denied Intermedics' new trial motion, adopted the jury's verdict, and entered an Amended Judgment on October 10, 1985 (A 17). Intermedics filed a timely appeal based in part on the erroneous exclusion of Mr. Gambrell's testimony.

In affirming, the CAFC admitted that Mr. Gambrell was a qualified expert, but concluded that the exclusion of his testimony, because he did not participate in the prosecution of the R/S patent, was within the district court's discretion (A 12). The CAFC added: "Moreover, the exclusion does not appear to be prejudicial since the testimony sought to be introduced was cumulative of testimony al-

ready in the record." This simply is not correct. As discussed later, the CAFC was led to this erroneous conclusion by an unsupported allegation by Medtronic and the CAFC's failure to review the record. Mr. Gambrell's testimony was not cumulative.

Since a patent has but one life, the R/S patent was extinguished without a full hearing. *Blonder-Tongue Laboratories, Inc. v. University of Illinois Found.*, 402 U.S. 313 (1971). Intermedics seeks a new, fair trial on the R/S patent by the grant of writ of certiorari or summary reversal pursuant to Supreme Court Rule 23.1.

REASONS FOR GRANTING THE WRIT

This case presents issues that affect virtually every type of federal civil jury case, have not been considered by this Court, and have been decided in conflicting fashion by the circuit courts. These issues compel a unified resolution by this Court.

Since the adoption of the Federal Rules of Evidence in 1975, this Court has not considered the evidentiary rules relating to expert testimony (Rules 702-4) or the exclusionary aspects of Rule 403 in a civil case. Today, at least one expert testifies in most civil jury trials. They are essential to help lay juries understand the litigated fact issues. *See* Rossi, *Modern Evidence and the Expert Witness*, 12 A.B.A.J. Sec. Lit. 18, 18-19 (Fall 1985).

In this case, the district court ignored Rule 703 and excluded relevant expert testimony. Thus the district court never made a Rule 403 analysis, which is required to ex-

clude relevant admissible evidence. The appellate court also ignored the requisite Rule 403 analysis and instead sought to justify the exclusion of this relevant testimony on the basis of harmless error. Yet the appellate court did so without considering any standard to determine harmless/prejudicial error.

First, a litigant should not be deprived of valuable expert testimony because of an incorrect interpretation of Rule 703. In its supervisory role over the trial of civil litigation and to ensure fair trials, this Court should send a clear mandate to the trial courts about the significance of Rule 703.

Second, the circuit courts have used Rule 403 in conflicting ways. Some recognize that if the trial court did not do the balancing required by Rule 403, the case must be remanded for a new trial. Other courts will play Monday-morning quarterbacks and perform the Rule 403 balancing. This Court must give the appellate courts guidance on this significant issue. Absent direction from this Court, the trial courts and appellate courts have unfettered discretion—which translates into an abuse of discretion without meaningful review.

Last, and possibly most significant, this Court has never considered the standard by which an appellate court should determine whether the error during a civil jury trial "does not affect the substantial rights of the parties." 28 U.S.C. § 2111; Fed. R. Civ. P. 61; Fed. R. Evid. 103. An acknowledged conflict exists among the circuit courts on the standard for harmless/prejudicial error. The need for a unified standard is also recognized by the commentators. *See, e.g.*, R. Traynor, *The Riddle of Harmless Error* 15 (1970) (*Traynor*). Such a standard would affect many litigated civil cases in the federal system.

I.

THE EXCLUSION OF MR. GAMBRELL'S TESTIMONY WAS MANIFEST ERROR UNDER RULE 703

Although the trial judge has discretion in the exclusion of expert evidence, *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962), the correct legal standards must be applied in the exercise of that discretion. *In re Japanese Elec. Prods. Antitrust Litig.*, 723 F.2d 238, 277-79 (3d Cir. 1983); *Mannino v. International Mfg. Co.*, 650 F.2d 846, 849 (6th Cir. 1981). If not, the exclusion of the expert testimony is erroneous. *Japanese Antitrust Litig.*, 723 F.2d at 277; *Mannino*, 650 F.2d at 849-53.

Rule 703 sets forth the legal standard for the bases of opinion testimony by experts. This rule plainly does not require the expert to have personal knowledge of, or have participated in, the events about which he will testify. Clearly, the district court applied the wrong legal standard in excluding Mr. Gambrell's testimony about the prosecution history of the R/S patent. *Barefoot v. Estelle*, 463 U.S. 880, 903-05 (1983); *Dixon v. International Harvester*, 754 F.2d 573, 580 (4th Cir. 1985); *Ramsey v. Culpepper*, 738 F.2d 1092, 1101 (10th Cir. 1984). In *Estelle*, this Court held that the expert testimony of psychiatrists who had not personally examined the defendant was properly admitted. 463 U.S. at 903-05.

Further, the appellate courts must determine whether the correct legal standards have been applied by the trial judge. *Mannino v. International Mfg. Co.*, 650 F.2d at 849. The CAFC did not perform its duty. Had it done so, it would have determined that the exclusion of Mr. Gambrell's testimony was based upon an erroneous legal standard.

II.

THE CAFC IGNORED RULE 403 AND THUS MADE A FLAWED ANALYSIS OF HARMLESS/PREJUDICIAL ERROR

Because Mr. Gambrell's relevant testimony was clearly admissible under Rule 703, the district court was required to admit it, unless it was excludable under Rule 403. Fed. R. Evid. 402; *Contemporary Mission, Inc. v. Famous Music Corp.*, 557 F.2d 918, 928 (2d Cir. 1977).

Under Rule 403, the trial judge is required to balance the probative value of the relevant evidence against one or more countervailing factors, including "needless presentation of cumulative evidence." Unless the probative value of the evidence is *substantially* outweighed by the countervailing factors, the judge must admit the evidence. *Contemporary Mission*, 557 F.2d at 928.

However, because the district court erroneously ruled that Mr. Gambrell's testimony was inadmissible under Rule 703, it never considered whether this evidence should be excluded under Rule 403, never considered whether this evidence was cumulative, and never weighed the probative value of this evidence, even if cumulative, on the Rule 403 scale, which is loaded in favor of admissibility. *Brooks v. Chrysler Corp.*, 786 F.2d 1191, 1198 (D.C. Cir.), *cert. denied*, 55 U.S.L.W. 3235 (1986); *Cook v. Spencer*, 688 F.2d 1017, 1017-18 (5th Cir. 1982). In short, the district court never exercised its discretion under Rule 403: "The *exercise* of a judge's discretion requires just that—exercise, application, overt action." *United States v. Lebovitz*, 669 F.2d 894, 902 (3d Cir.) (Adams, J., concurring) (emphasis in original), *cert. denied*, 456 U.S. 929 (1982).

Without the benefit of any Rule 403 analysis by the trial court, some circuit courts have concluded that it is an in-

appropriate exercise of appellate power to do the first Rule 403 analysis. These courts merely reverse and remand for a new trial. *United States v. Downing*, 753 F.2d 1224, 1243 (3d Cir. 1985); *United States v. Layton*, 720 F.2d 548, 563 (9th Cir. 1983), *cert. denied*, 465 U.S. 1069 (1984); *Miller v. Poretsky*, 595 F.2d 780, 794 (D.C. Cir. 1978) (concurring opinion adopted by majority at 785); *Contemporary Mission*, 557 F.2d at 928.

Other circuit courts will engage in such hindsight Rule 403 analysis. *United States v. Schwartz*, 790 F.2d 1059, 1062 (3d Cir. 1986); *United States v. Burke*, 781 F.2d 1234, 1242-43 (7th Cir. 1983); *Harpring v. Continental Oil Co.*, 628 F.2d 406, 410 (6th Cir. 1980), *cert. denied*, 454 U.S. 819 (1981).

The CAFC took a third approach—it ignored Rule 403. The CAFC simply labeled Mr. Gambrell's testimony as "cumulative" and therefore concluded that its exclusion "does not appear to be prejudicial" (A 12).

The CAFC was lead to this erroneous "cumulative" premise by blindly adopting Medtronic's undocumented assertions. In its Brief, Medtronic did not cite a single instance in which *any* witness testified about the prosecution history of the R/S patent. Instead, Medtronic merely *alleged*:

> Mr. Gambrell's intended testimony was repetitive of testimony offered by Drs. Rasor, Spickler, Williams and Tyers, and by Messrs. Stokes, Citron and Terry, among others [MB 45].

The CAFC's opinion adopted this false assertion *verbatim* (see n.21, A 12), without any citation to the alleged cumulative testimony.

Obviously, the CAFC failed to review the record, *because Dr. Williams and Messrs. Stokes and Citron were*

Medtronic's witnesses. Certainly Medtronic's witnesses did not testify as Mr. Gambrell would have testified (see Intermedics' offer of proof, A 21-25), or Intermedics would have been entitled to a directed verdict.

If the CAFC had reviewed the record, it would have realized that there was no testimony about the prosecution history of the R/S patent, since Messrs. Gambrell and Banner were the only witnesses qualified to do so. Thus Mr. Gambrell's testimony would not have been cumulative.

Moreover, even if Mr. Gambrell's testimony was partially cumulative and the appellate courts may perform the first Rule 403 balancing, the CAFC did not do so. Despite repeated holdings about the relevance of the file history to the validity and infringement issues, *e.g.*, *Moeller*, 794 F.2d at 656; *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569-71 (Fed. Cir. 1983), the CAFC never weighed the probative value of Mr. Gambrell's testimony against its possible cumulative effect. The CAFC merely said the evidence was cumulative, as though that fact alone justified its exclusion.

III.

THE ERRONEOUS EXCLUSION OF MR. GAMBRELL'S TESTIMONY WAS PREJUDICIAL ERROR

A. The Circuit Courts Have Used Conflicting Standards To Determine Harmless/Prejudicial Error

Errors are harmless if they "do not affect the substantial rights of the parties." 28 U.S.C. § 2111; Fed. R. Civ. P. 61; Fed. R. Evid. 103. This Court has not formulated the standard to determine harmless/prejudicial error in a civil case. The circuit courts have groped for the answer, but the result has been conflict and confusion.

The Ninth Circuit has adopted this harmless/prejudicial error standard: An error is harmless if it is *more probable than not* that the jury's verdict was not affected by the error. *Haddad v. Lockheed California Corp.*, 720 F.2d 1454, 1459 (9th Cir. 1983).

The Third Circuit has specifically rejected the Ninth Circuit's standard and reasoning and adopted the following standard: An error is harmless, if it is *highly probable* that the jury's verdict was not affected by the error. *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 923-28 (3d Cir. 1985).

Apparently, the Eighth Circuit has adopted the Ninth Circuit's "more probable than not" standard. *McIlroy v. Dittmer*, 732 F.2d 98, 105 (8th Cir. 1984); *see also E.I. du Pont de Nemours v. Berkley & Co.*, 620 F.2d 1247, 1257-58 (8th Cir. 1980). However, this standard was not applied by the *McIlroy* panel two weeks later. *Rosebud Sioux Tribe v. A & P Steel, Inc.*, 733 F.2d 509, 517-18 (8th Cir.), *cert. denied*, 105 S. Ct. 565 (1984) (error is prejudicial where the obvious result would be a plain miscarriage of justice or be inconsistent with substantial justice). Also, the Eighth Circuit has special standards that it applies in certain situations. *See Lovett v. Shuster*, 633 F.2d 98, 103 (8th Cir. 1980) (erroneous reception of evidence in non-jury case); *E.F. Hutton & Co. v. Berns*, 682 F.2d 173, 177 (8th Cir. 1982) (erroneous jury instructions).

Although the Fifth Circuit has not clearly articulated the degree of probability necessary to determine if an error is harmless, most panels of the Fifth Circuit seem to have adopted a "highly probable" standard. *Dartez v. Fibreboard Corp.*, 765 F.2d 456, 468-69 (5th Cir. 1985); *Pregeant v. Pan American World Airways, Inc.*, 762 F.2d 1245, 1249 (5th Cir. 1985); *O'Rear v. Fruehauf Corp.*, 554

F.2d 1304, 1308-09 (5th Cir. 1977). However, at least one panel of the Fifth Circuit has employed what seems to be a "more likely than not" standard. *Johnson v. William C. Ellis & Sons Iron Works, Inc.*, 604 F.2d 950, 958, 960 (5th Cir. 1980), *modified on other grounds*, 609 F.2d 820 (5th Cir. 1980).

The other circuit courts have applied a variety of harmless/prejudicial error standards. *See, e.g., Sims Consol., Ltd. v. Irrigation and Power Equip., Inc.*, 518 F.2d 413, 418 (10th Cir.), *cert. denied*, 423 U.S. 913 (1975) (the exclusion of evidence "is not grounds for reversal unless it can be reasonably said that the evidence was competent and that its exclusion precluded a fair trial"); *Perry v. Larson*, 794 F.2d 279, 285 (7th Cir. 1986) (to be prejudicial the error must be substantial enough to deny the litigant a fair trial); *International Merger & Acquisition Consultants, Inc. v. Armac Enters., Inc.*, 531 F.2d 821, 823 (7th Cir. 1976) (error is harmless if it in no way influenced the jurors or had but slight effect on them); *Collum v. Butler*, 421 F.2d 1257, 1260 (7th Cir. 1970) (error is harmless if results of the trial were not substantially effected by error); *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 837 (2d Cir. 1967) (error is harmless if the jury's finding was not significantly influenced by the error); *International Bureau, Inc. v. Bethlehem Steel Co.*, 192 F.2d 304, 306 (2d Cir. 1951) (error is harmless unless it is reasonable to believe that the granting of new trial would be likely to change the result); *Miller v. Poretsky*, 595 F.2d at 786 (error is prejudicial if the average jury would be swayed in its decision by the error). *See also generally, Traynor* at 17-37.

The CAFC did not disclose what standard, if any, it used to determine harmless/prejudicial error. It simply stated that the exclusion of Mr. Gambrell's testimony "does not *appear* to be prejudicial" (A 12) (emphasis

added). However, the CAFC has held that, with respect to procedural matters, it will apply the law of the circuit court in which the district court resides. *DMI, Inc. v. Deere & Co.*, 231 USPQ 276, 280-81 (Fed. Cir. 1986); *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574-75 (Fed. Cir. 1984).

In view of the conflict and confusion among the circuit courts about the harmless/prejudicial error standard, the CAFC will be applying different standards in different cases. Thus in due course the CAFC could, based on the identical error, find harmless error in a case from one circuit and prejudicial error in a case from another circuit. This could result in the introduction of different evidence in cases involving the same patent and could lead to different results in those cases. However, that would be contrary to the purpose of the CAFC: to unify the results in patent cases. *Panduit*, 744 F.2d at 1573-74. Thus, the unique position of the CAFC highlights the seriousness of the conflict among the circuits.

Intermedics submits that the "highly probable" standard is the correct standard for the reasons set forth in *Traynor* at 34-36. In any event, Intermedics urges this Court to set a clear standard for the lower courts and litigants.

B. Without Doubt The Exclusion Of Mr. Gambrell's Testimony Was Prejudicial Error

Under any standard, the exclusion of Mr. Gambrell's testimony was prejudicial error. Mr. Gambrell was a key expert witness on the validity and infringement issues of the R/S patent. The exclusion of his testimony prevented Intermedics from having a full hearing on the R/S patent. Under those circumstances, the exclusion of expert testi-

mony is clearly prejudicial error. *See Shad v. Dean Witter Reynolds, Inc.*, 799 F.2d 525, 530 (9th Cir. 1986); *Traynor* at 68-69.

Although Mr. Gambrell would have testified about several matters (A 21-24), a discussion of one issue, claim construction, will serve to demonstrate the prejudicial impact of the exclusion of his testimony. It is axiomatic that the claims of a patent must be construed in light of the specification and prosecution history of the patent. *See, e.g., Moeller*, 794 F.2d at 656; *Fromson*, 720 F.2d at 1569-71. Claim construction relates to both the issues of validity and infringement.

Mr. Gambrell would have explained how the prosecution history of the R/S patent affected the construction and scope of the asserted claims. He would have explained why, based upon the prosecution history, the claims of the R/S patent could not be construed in the manner argued by Medtronic. He also would have explained why the claims, as properly construed, were valid and infringed. (A 21-24) No witness testified about these matters.

Mr. Gambrell was admittedly qualified to testify about claim construction and the other matters listed in the Statement Of The Case, *supra* p. 4. His analysis would have differed from that of any other Intermedics witness since his testimony would have included an analysis of the prosecution history and because none of those other witnesses was knowledgeable about PTO procedure and patent law. To the extent that his testimony was partially cumulative of Intermedics' other witnesses, it was *not* needlessly so because it provided corroboration of their opinions from a different viewpoint. Fed. R. Evid. 403.

Indeed, other courts having the benefit of Mr. Gambrell's testimony on such issues have found it to be "vital

and of great importance," *U.S. Indus., Inc. v. Norton Co.*, 578 F. Supp. 1561, 1567-68 (N.D.N.Y. 1984), and "credible and convincing." *Kori Corp. v. Wilco Marsh Buggies and Draglines, Inc.*, 561 F. Supp. 512, 520 (E.D. La. 1981), *aff'd*, 708 F.2d 151 (5th Cir. 1983), *transferred and aff'd*, 761 F.2d 649 (Fed. Cir.) (damages), *cert. denied*, 106 S. Ct. 230 (1985).

The lay jury had no knowledge of the intricacies of the patent system and could not reasonably be expected to reach informed decisions on validity and infringement without the testimony of a patent expert like Mr. Gambrell. If the district judges in *Norton* and *Kori* found Mr. Gambrell's testimony to be helpful, then clearly the lay jury in this case needed his testimony. Indeed patent experts have testified in the vast majority of the patent jury trials reviewed by the CAFC (JA 130.1).

Medtronic's counsel admitted the usefulness of such expert testimony in his opening statement (JA 141-42). Indeed, Medtronic and its counsel in other jury cases have used patent expert testimony on the same matters proffered by Intermedics. *See, e.g., Medtronic, Inc. v. Catalyst Research Corp.*, 547 F. Supp. 401 (D. Minn. 1982); *Goldberg v. Medtronic, Inc.*, 209 USPQ 259 (N.D. Ill. 1980), *aff'd*, 686 F.2d 1219 (7th Cir. 1982).

Under any standard of harmless error, the exclusion of Mr. Gambrell's testimony kept crucial, relevant evidence from the jury and deprived Intermedics of a fair trial. The effect of the error was almost certainly significant, and Intermedics' substantial rights have been prejudicially affected. *See Memphis Community School Dist. v. Stachura*, 54 U.S.L.W. 4771, 4774 (1986).

CONCLUSION

For the foregoing reasons, Petitioner asks the Court to grant the writ, vacate the judgment of the CAFC, and remand this case to the district court for a new trial on the R/S patent. In the event the writ is not granted, Petitioner asks the Court to grant summary reversal and remand pursuant to Supreme Court Rule 23.1.

Respectfully submitted,

ROY E. HOFER
One IBM Plaza, Suite 4100
Chicago, Illinois 60611
(312) 822-9800
Attorney for Petitioner

Of Counsel:
WANNELL M. CROOK
HAROLD V. JOHNSON
WILLIAN BRINKS OLDS HOFER
GILSON & LIONE LTD.

APPENDIX

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Appeal No. 86-647

MEDTRONIC, INC., and MED REL, INC., and MEDTRONIC PUERTO RICO, INC.,

Appellees,

v.

INTERMEDICS, INC.,

Appellant.

DECIDED: August 15, 1986

Before DAVIS, *Circuit Judge,* COWEN, *Senior Circuit Judge,* and NEWMAN, *Circuit Judge.*

DAVIS, *Circuit Judge.*

This case, coming from the United States District Court for the Southern District of Texas, concerns two separate patents, one owned by appellee Medtronic, Inc. and its wholly-owned subsidiary Medtronic Puerto Rico, Inc. (collectively called Medtronic), and the other by appellant Intermedics, Inc. (Intermedics). Medtronic's patent was upheld and Intermedics' was ruled invalid. Intermedics is the only appellant. Medtronic's patent (which was upheld and found infringed) is U.S. Patent No. 3,902,501 (the C/D patent).[1]

---

[1] U.S. Patent No. 3,902,501 issued to Paul Citron and Eugene A. Dickhudt on September 2, 1975 and was assigned to Medtronic.

It was considered (and held not invalid) in this court's recent decision in *Medtronic, Inc. v. Daig Corporation*, 789 F.2d 903 (Fed. Cir. 1986), *reh'g denied*, No. 85-2645 (July 1, 1986). Intermedics' patent is U.S. Reissue Patent No. 30,366[2] (the R/S patent) held invalid by the District Court under 35 U.S.C. § 103, and not infringed by Medtronic. We affirm.

I. BACKGROUND

A. *The Inventions*

The case relates, as did *Medtronic v. Daig, supra*, to pacemaker leads which comprise an electrode tip at one end for electrically connecting the heart to a pulse generator. The entire system of lead, generator and a power source is called a "pacemaker." In use, electrical impulses cause the heart to beat, thus restoring an acceptable heart rate to a patient whose heart rate is too low or erratic.

The two major types of pacemaker leads are the endocardial lead and the epicardial (myocardial) lead. The epicardial lead is affixed to the outside tissue of the heart. Such fixation requires a major surgical procedure and is disadvantageous because of attendant trauma to the patient, extended recuperation time, as well as the risks associated with major surgery.

Endocardial leads are inserted inside the heart through a vein. These leads alleviate the problems accompanying epicardial leads because implantation inside the heart involves a relatively non-traumatic surgical procedure under local anesthesia.

---

[2] Reissue Patent No. 30,366 reissued to Ned S. Rasor and Joseph W. Spickler, the inventors named in the original patent, U.S. patent No. 3,835,864, which issued on September 17, 1974.

Both patents in this suit relate to endocardial leads for transvenous implantation, each having a pacing electrode at its distal tip. The lead of the C/D patent comprises soft, pliant tines near the electrode tip which entangle or cooperate in the stringlike "trabeculae"[3] of the heart's interior, thus providing a means of passively fixing the electrode to the heart.[4] The C/D patent teaches that its tined leads address the dislodgment problem of prior art leads while minimizing trauma and preserving acute repositionability.

The R/S patent provides for an endocardial lead comprising

> electrode means . . . for contact with a portion of the living body to be stimulated by said electrode means, and means mounted to project outwardly of and peripherally of said body form including anchor portions locating in a position displaced from said electrode means and providing means for engaging in portions of said living body to establish said electrode means in a required position of use . . . .

---

[3] Trabeculae are lattice-like structures or small bundles of muscle fiber in the ventricular apex or the right atrial appendage.

[4] Claim 1, involved here, is representative:

> 1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises: non-conducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

R/S patent, Claim 1, Column 11, lines 13-21. The R/S patent discloses an active fixation using wires or barbs to hook into the heart muscle.[5] Among the objects advanced in the R/S patent was the attachment of an endocardial lead in a region spaced away from the region of stimulation to avoid the adverse effects of tissue fibrosis.[6]

B. *District Court proceedings*

Medtronic initiated this action on November 7, 1980 against Intermedics for infringement of the former's C/D patent. Intermedics counterclaimed for infringement by Medtronic of the R/S patent.

The case was tried before a jury. Returning answers to sixteen special interrogatories which sought certain factual answers relating to obviousness, as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), as well as to infringement, the jury rendered its verdict on August 2, 1983.[7] The jury returned answers to these interrogatories that Medtronic's C/D patented invention would not have been obvious and was infringed by Intermedics and that Intermedics' R/S patent was invalid and not infringed.

Following the verdict, Intermedics moved for a new trial on the C/D patent based on allegedly newly discovered

---

[5] *See* Column 3, line 16; Column 5, lines 50-51; and Column 7, lines 55-58 of the R/S patent.

[6] Fibrosis relates to the growth of fibrotic or scar tissue and decreases the ability of the heart tissue to be stimulated.

[7] The interrogatories covered, *inter alia*, the obviousness of both patented inventions, the commercial success of and need for each patented invention, and the main difference between the prior art and each invention.

evidence of prior invention, and other grounds. The trial judge, Judge Gibson, denied Intermedics' new trial motion[8] and entered a judgment of validity and infringement on August 16, 1985. Next, Intermedics moved for a judgment notwithstanding the verdict (JNOV) under Fed. R. Civ. P. 59; this motion challenged the jury's verdicts as to invalidity and infringement of both patents. The motion was denied on October 4, 1985.

Intermedics now argues that the trial judge erroneously adjudged the R/S patent invalid and the C/D patent not proven invalid, and erroneously denied the motion for JNOV on the issue of infringement of the R/S patent. In addition, Intermedics contends that there were prejudicial errors committed during the trial which warrant a new trial on any validity or infringement issue not resolved in its favor.

II. *Validity*

In assessing nonobviousness a number of factual inquiries must of course be made: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of secondary considerations such as long felt need, unexpected results or

---

[8] Judge Gibson held in abeyance his decision on the new trial motion until the evidence concerning the alleged prior invention had been considered by the federal District Court in Minnesota. In August 1985, Judge Earl Larson of the United States District Court for the District of Minnesota held the C/D patent valid and infringed by two other competitors of Medtronic. *Medtronic, Inc. v. Daig Corp.*, 611 F. Supp. 1498, 227 U.S.P.Q. 509 (D. Minn. 1985), *affirmed*, 789 F.2d 903, *supra*. Judge Larson rejected as not credible the prior-invention evidence on which Intermedics based its new trial motion.

commercial success. *Graham*, 383 U.S. at 17, 148 USPQ at 467. With respect to both patents, the parties agreed or stipulated the first and second of the factual inquiries set forth in *Graham*. Only issues relating to the third and fourth factual inquiries were submitted for jury decision. *See supra* note 7. On these issues, the jury findings must stand unless they are unsupported by substantial evidence of record. *Structural Rubber Products v. Park Rubber*, 749 F.2d 707, 719, 223 USPQ 1264, 1273 (Fed. Cir. 1984); *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512, 220 USPQ 929, 936 (Fed. Cir.), *cert. denied*, 105 S. Ct. 220, 224 USPQ 520 (1984).

1. *The C/D patent*

On this appeal, Intermedics does not contest the *Graham* factual inquiries stipulated by the parties or decided by the jury; rather, Intermedics disputes only the ultimate conclusion of nonobviousness with respect to claims 1 and 7 of the C/D patent. Obviousness is a question of law. In reviewing a District Court's refusal to grant JNOV, it is the duty of this court to be satisfied that the law has been correctly applied to the facts found. *Structural Rubber Products*, 749 F.2d at 719, 223 USPQ at 1273; *Railroad Dynamics, Inc.*, 727 F.2d at 1512, 220 USPQ at 936.

Prior art advanced against the C/D patent included the 1969 Schaldach, et al., reference,[9] and the Rasor/Spickler article.[10] These articles were not before the Patent and

[9] Schaldach, M. & Franke, O., "Technischer Stand und Tendenzen in der Schrittmachertherapie," Mediginal-MarkT/Acta Medicotechnica, Nr. 6 (1969).

[10] Spickler, W. J., Rasor, N. S., Kezdi, P., Misra, S.N., Robins, K.E., & LeBouef, C., "Totally Self-Contained Intracardiac Pacemaker," J. Electrocardiology, 3 (3-4) 325-331, (1970).

Trademark Office (PTO) during the prosecution of the C/D patent. The Schaldach article taught an endocardial lead having pliant metal tines which were adjacent to the electrode tip and which engaged themselves in the trabeculae. The Rasor/Spickler article disclosed an intracardial pacemaker with radiating fingers that were intended to catch in the trabeculae of the ventricle.[11] Neither of these prior art articles expressly taught pliant tines which were made of soft material.

The jury found that the soft pliant tines which did not penetrate tissue and which cooperated with the heart constituted the difference between the claims of the C/D patent and the prior art.[12] As Intermedics recognizes, this finding was supported by substantial evidence. Neither Dr. Rasor nor Dr. Spickler could recall specifically what material composed radiating fingers in any of the devices proposed by the R/S article. Testimony ranged from nylon to surgical gut. Dr. Rasor also admitted that he did not promote "soft flexible fingers" in any publication or abstract, or in approaching potential licensees. When asked if he ever proposed the use of soft tines for a lead to the National Heart Institute even as late as 1973, Dr. Rasor testified as follows:

Q: Did you ever make a proposal to them that it would be nice to have soft, flexible fingers?
A: Not in those terms.
Q: All right.
A: And to them—will you specify who you meant?

---

[11] The ventricles are the lower chambers of the heart which receive blood from a corresponding atrium (the upper chambers of the heart) and from which blood is forced into the arteries.

[12] The jury also found expressly that Rasor and Spickler had not made an invention of a lead having soft, pliant tines prior to the C/D invention.

Q: To anyone.
A: Not in those terms.

Jt. App., Vol. IV, A 1058.

Intermedics argues that the testimony of its expert, Dr. Tyers, established that (1) the radiating finger in the Rasor/Spickler article appeared non-metallic in view of the difference in reflectiveness between the fingers and surrounding metal and (2) that the fingers had to be pliant in order to be inserted into the vein. However, the jury was free to discount this evidence as showing soft or pliant tines, in favor of other credible evidence that Citron and Dickhudt first conceived the invention.

The jury also found that the soft pliant tines of the C/D patent satisfied a long felt need and achieved commercial success.[13] Even though the level of skill in the art was stipulated to be high,[14] we hold that the jury findings and the facts as agreed upon by the parties support the District Court's legal conclusion that the C/D patent was not proven invalid. *See Medtronics, Inc. v. Daig Corp., supra.*

---

[13] Though the absence of objective evidence is a neutral factor, if present it "may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983); *see also Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 219 USPQ 857 (Fed. Cir. 1983).

[14] The "level of skill" as set by stipulation of the parties was a "person having the combination of skill and knowledge of a cardiac surgeon together with the expertise of biomedical engineer having a mechanical or electrical aptitude or engineering degree."

2. *The R/S patent*

The District Court found claims 1, 2 and 5 of the R/S patent invalid for obviousness under 35 U.S.C. § 103 over prior art of record. Intermedics challenges this ultimate conclusion of obviousness. Also, Intermedics attacks the jury findings with respect to the secondary considerations of non-obviousness—here, the absence of commercial success, the non-satisfaction of a long felt need—claiming that they were unsupported by substantial evidence.

A prima facie case of obviousness of the R/S patent invention was essentially made by combining two references, the 1968 Parsonnet, et al. article[15] and the 1969 Schaldach, et al. article.[16] Basically, the same prior art was before the PTO. The Parsonnet article taught flanged leads which included a frustoconical flange as a means to catch in the trabeculae and hold the lead in place, and, as such, provided passive fixation remote from the point of stimulation. The Schaldach article taught an endocardial safety pin type lead which had two metal barbs or wire hooks extending outwardly from the electrode tip, and thus provided a fixation means extending outwardly from the body as required by the challenged claims of the R/S patent. Here, again, the stipulated level of skill was high.[17]

The jury found "that the difference between the prior art and the space anchored electrode of the R/S patent was the provision of anchors which projected outwardly

---

[15] Parsonnet, V., Zucker, I.R., Gilbert, L. Rothfeld, E.L., Alpert, J., and Brief, D.K., "Clinical Experience with Implanted Standby Pacemakers," SURGERY, Vol. 63, No. 1, pp. 188-197 (1968).

[16] *See supra* note 9.

[17] *See supra* note 14.

from the body of the lead and are spaced from the electrode tip."[18] This finding is not disputed. The prior art references in combination clearly showed that the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. We take this position especially in light of evidence which showed that Intermedics produced the leads of the R/S patent by engrafting tines on its earlier flanged leads and that it advertised the use of the flange together with the tines to provide "two anchoring mechanisms."[19] We are satisfied that the jury findings, the stipulated facts, and the evidence of record support the District Court's denial of JNOV and conclusion that one skilled in the art would have been led by the prior art to position the anchor means outwardly from the heart and to use the flange of the lead, as disclosed in the R/S patent, to provide a mechanism to anchor the lead remote from the point of stimulation. We also think that the jury's finding of the absence of the satisfaction of a long-felt need was supported by substantial evidence of record.[20]

---

[18] Jury Interrogatory No. 11, at Jt. App., Vol. 1, A 79.

[19] *See* Testimony of Anson K. Atkinson, Vice President of Marketing at Intermedics, at Jt. App., Vol. III, A 506-508.

[20] Intermedics asserts that its spaced anchor electrode structure satisfied a long felt need for low threshold electrodes. However, there was credible evidence to the contrary. For example, Ken Stokes, an engineer, reviewed the threshold results obtained from a number of different leads and concluded that there is no correlation between point of fixation and thresholds. Jt. App., Vol. III, A 686. Dr. Martin, Intermedics' Executive Vice President also admitted that tined leads do not achieve lower threshold. Jt. App., Vol. II, A 440-42. Other credible evidence established that conventional Medtronic and Cordis flanged endocardial leads, that were available at the time of Spickler's work, were achieving thresholds lower than those publicized by Rasor and Spickler. Jt. App., Vol. V, A 1358-60. (Testimony of Hellard, engineer at Medtronics.)

Further, Intermedics has failed to show that there was no substantial evidence supporting the jury finding of lack of commercial success. Intermedics argues that the R/S patent received at least one million dollars in monetary tribute. But there was no evidence relating this tribute to the amounts of sales of the R/S device or suggesting that any sales were due to the inclusion of the claimed features of the R/S patent. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315, 227 USPQ 7[6]6, 770 (Fed. Cir. 1985) (for a claimed invention's commercial success to be given substantial weight, a nexus must be established between it and the merits of the claimed invention).

III. *Infringement*

Intermedics does not challenge, as a matter of law, the finding of its infringement with respect to the C/D patent. However, Intermedics does argue that the jury finding of non-infringement of the R/S patent is not supported by substantial evidence. Because we have concluded that the District Court correctly decided that the R/S patent was invalid for obviousness, we need not and do not decide the issue of infringement. In the succeeding section of this opinion, we do, however, address Intermedics' contentions that the denial of its motions for a new trial and for judgment notwithstanding the verdict (with respect to infringement of the R/S patent), was erroneous.

IV. *New trial and judgment notwithstanding the verdict*

A. *Denial of new trial motions*

Errors in judicial rulings or in the conduct of the court warrant a new trial where the error or conduct was prejudicial. 6A J. Moore, Moore's Federal Practice § 59.08(2)

(2d ed. 1983). Review of the denial or grant of a motion for new trial is evaluated under an abuse of discretion standard. *Id.* at § 59.08. Intermedics has asserted two grounds for a new trial: (1) the improper exclusion of evidence, and (2) the giving of erroneous jury instructions.

Exclusion of Evidence: The excluded evidence of which Intermedics chiefly complains was the testimony of its patent expert, Professor Gambrell. While Professor Gambrell did testify at trial, a portion of his testimony relating to the explanation and discussion of the prior art, the scope and obviousness of the asserted claims, and the infringement of the asserted claims, was excluded, apparently because Professor Gambrell did not personally have knowledge of the prosecution of the patents in suit but would testify generally about patent law with respect to its application to this case.

We do not think that the trial judge abused his discretion in the exclusion of this evidence. Professor Gambrell was qualified as an expert and, as such, was allowed to testify at trial. The trial judge, in his discretion, simply circumscribed the extent of Professor Gambrell's testimony on the basis of the witness's range of expertise with respect to the two patents and the prior art in this suit. Moreover, the exclusion does not appear to be prejudicial since the testimony sought to be introduced was cumulative of testimony already in the record.[21] We also see no abuse of discretion in the trial judge's exclusion of evidence relating to the amount of the settlement offer made by Medtronics. "An offer of settlement is not admissible to prove liability." Fed. R. Evid. 408.

---

[21] Mr. Gambrell's intended testimony was repetitive of testimony offered by Drs. Rasor, Spickler, Williams and Tyers, and by Messrs. Stokes, Citron and Terry, among others.

Jury Instructions: The jury was charged that the burden of proving invalidity of a patent was "clear and convincing" unless the jury found the art cited in the litigation to be more pertinent than that cited to the PTO; in that event, the burden was a preponderance of evidence. This instruction was erroneous. 35 U.S.C. § 282 creates a presumption that a patent is valid and imposes the burden of proving invalidity on the challenger by "clear and convincing evidence." That burden is permanent and does not change. However, Intermedics did not object to these instructions at trial and cannot now assert error respecting them, absent a showing of "great injustice." *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 730 F.2d 604, 615, 222 USPQ 654, 662 (Fed. Cir.), *cert. denied*, 105 S. Ct. 516 (1984) (citing *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1364, 220 USPQ 763, 774 (Fed. Cir.), *cert. denied*, 105 S. Ct. 95 (1984)). *See* Fed. R. Civ. P. 51.

There was no "great injustice." With respect to the obviousness of the R/S invention, the most pertinent art was before the PTO; thus, the burden was correctly "clear and convincing."[22] As for the C/D patent, Intermedics failed to prevail on the lower burden of a preponderance of evidence—charged by the District Court—and has plainly failed to show that it would have prevailed under the stronger burden. In these circumstances, there is no harmful error.

Regarding infringement, the record shows that Intermedics timely objected to instructions relating to infringement but only on the ground that, under the facts of this case, there was no need to instruct the jury on the mat-

---

[22] *See Atlas Powder Co. v. E.I. Dupont de Nemours & Co.*, 750 F.2d 1569, 1573, 224 USPQ 409, 411 (Fed. Cir. 1984); and *American Hoist*, 725 F.2d at 1358, 1360, 220 USPQ at 764, 771.

ter of equivalency. Claim 1 of the R/S patent calls for a "means" for performing a specified function, *i.e.*, engaging in portions of a living body. Under 35 U.S.C. § 112, ¶ 6, such a claim must be construed in light of the specification to cover the corresponding means structure and "equivalents thereof." It was necessary to instruct the jury on equivalency so that they could properly determine the equivalency of the "means" of the R/S patent claims and Medtronics' tine leads. We see no error in these instructions relating to the meaning of equivalent structures. In construing a "means plus function" claim, a number of factors, including the language of the claim, the patent specification, the prosecution history of the patent, other claims in the patent, and expert testimony may be considered. *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 975, 226 USPQ 5, 8 (Fed. Cir. 1985) (citing *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 221 USPQ 945 (Fed. Cir.), *cert. denied*, 105 S. Ct. 514 (1984)); *SRI International v. Matsushita Electric Corp.*, 775 F.2d 1107, 227 USPQ 577 (Fed. Cir. 1985). *See also D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574, 225 USPQ 236, 238 (Fed. Cir. 1985) (§ 112, ¶ 6 of 35 U.S.C., was written precisely to avoid a holding that a means-plus-function limitation must be read as covering only the means disclosed in the specification).

B. *Denial of Judgment Notwithstanding the Verdict (JNOV)*[23]

In considering a motion for JNOV, the District Court must: (1) consider all the evidence; (2) in a light most

[23] We have already considered the denial of the JNOV except for Intermedics' claim that Medtronics infringed the R/S patent. Technically it is unnecessary to consider this question because we have held that patent invalid. Nevertheless, we discuss this matter for the purpose of completeness.

favorable to the non-mover; (3) drawing reasonable inference favorable to the non-mover; (4) without determining credibility of witnesses; and (5) without substituting its choice for that of the jury between conflicting testimony. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1547, 220 USPQ 193, 197 (Fed. Cir. 1983). If the court determines that the evidence and inferences reasonably drawn therefrom, viewed in a light most favorable to the non-moving parties, substantially support the jury verdict, the motion for JNOV should be denied.

Intermedics argues that the testimony of its witness, Dr. Tyers, explained how claims 1, 2 and 5 of the R/S patent unequivocally read directly on Medtronics' tined lead and that Medtronics submitted no evidence in rebuttal. In interrogatory No. 2, the jury found that Rasor and Spickler did not invent soft, pliant tines which did not penetrate the heart tissue but cooperated with that tissue to hold the leads in place. There is, as we have already said, substantial support for that finding. The R/S patent disclosed barb-like means for attaching the lead which "tend to imbed themselves within the heart muscle."[24] The patent also stated that "if necessary, some pull could be placed on the lead to complete the attachment."[25] As to that passage, Dr. Martin testified as follows:

> Q: Is that a good idea?
> A: No.

Other parts in the R/S patent specification which permitted the jury to construe the "means" limitations of the R/S claims were "tissue-attaching member," "stain-

[24] The R/S Patent, col. 9, lines 62-65 and Col. 10, lines 16-20.
[25] The R/S Patent, col. 10, lines 20-22.

less steel attaching point," and "barbs."[26] There was, in short, substantial evidence for the jury's finding that Medtronics had not infringed the R/S patent (if it is deemed valid).

On the basis of all the evidence, the District Court did not err in its denial of Intermedics' motion for JNOV on the infringement of the R/S patent.

Finally, Intermedics contends that the District Court denied the motions for new trial or JNOV without written analysis. In view of the instructions which carefully laid out the verdicts if specific facts were found, and the special interrogatories answered by the jury in returning its verdict, we think that the record clearly delineates the basis for the District Court's decisions. There was no error in the summary denial of the motions.

AFFIRMED.

[26] The R/S Patent, col. 3, line 18; col. 4, line 21; and col. 7, line 49, respectively.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

MEDTRONIC, INC. and MEDTRONIC PUERTO RICO,
Plaintiffs, Counter-Defendants,

vs.

INTERMEDICS, INC.,
Defendant, Counter-Plaintiff.

Civil Action No. G-80-295
CONSOLIDATED W/G-80-294
Judge Gibson

AMENDED JUDGMENT

This Court having considered Plaintiff's Motion for Entry of Judgment and Permanent Injunction including a request to deny Defendant's Motion for New Trial, having considered the arguments of the parties and having presided over a trial of this cause to a jury, the jury having rendered its verdict, it is hereby

ORDERED, ADJUDGED AND DECREED as follows:

1. Medtronic, Inc. and Medtronic Puerto Rico, Inc. are, by assignment, the owners of all right, title and interest in and to United States Patent No. 3,902,501.

2. Claims 1 and 7 of United States Patent No. 3,902,501 are valid and enforceable against Intermedics, Inc.

3. The manufacture, use or sale by Intermedics, Inc. of its tined leads including Models 476-01, 476-02,

477-01, 477-02, 477-05, 484-01, 487-02, 483-01, 483-02, 483-03, 483-04, 490-01, 492-01, 486-01, 493-01, 493-02, 493-03, 495-01, and 496-01 have infringed claims 1 and 7 of United States Patent No. 3,902,501.

4. The manufacture, use or sale by Intermedics, Inc., its officers, agents, servants, employees and attorneys and all persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, of any tined endocardial lead that infringes claim 1 or claim 7 of United States Patent No. 3,902,501 is permanently enjoined. This injunction is to be effective September 9, 1985; provided, however, if the parties cannot agree upon the conditions of a stay of this injunction pending appeal and Intermedics files a Motion To Stay on or before September 9, 1985, this injunction will be stayed until there has been a ruling upon that Motion.

5. Intermedics, Inc. is the owner of all right, title and interest in and to United States Patent No. Re 30,366.

6. Claims 1, 2 and 5 of United States Patent No. Re 30,366 are invalid and not infringed by Medtronic, Inc. or Medtronic Puerto Rico, Inc.

7. This Judgment is entered nunc pro tunc to be effective October 4, 1985.

ENTERED this 10th day of October, 1985

/s/ HUGH GIBSON
United States District Judge

APPROVED AS TO FORM:

/s/ SAMUEL B. KENT
Attorney for Plaintiffs

/s/ ROY E. HOFER
Attorney for Defendant

STATUTORY PROVISIONS INVOLVED

28 U.S.C. §2111. Harmless error.

On the hearing of any appeal or writ of certiorari in any case, the court shall give judgment after an examination of the record without regard to errors or defects which do not affect the substantial rights of the parties.

Federal Rule of Evidence 103. Rulings on Evidence.

(a) Effect of erroneous ruling. Error may not be predicated upon a ruling which admits or excludes evidence unless a substantial right of the party is affected, and

(1) Objection. In case the ruling is one admitting evidence, a timely objection or motion to strike appears of record, stating the specific ground of objection, if the specific ground was not apparent from the context; or

(2) Offer of Proof. In case the ruling is one excluding evidence, the substance of the evidence was made known to the court by offer or was apparent from the context within which questions were asked.

(b) Record of offer and ruling. The court may add any other or further statement which shows the character of the evidence, the form in which it was offered, the objection made, and the ruling thereon. It may direct the making of an offer in question and answer form.

(c) Hearing of jury. In jury cases, proceedings shall be conducted, to the extent practicable, so as to prevent inadmissible evidence from being suggested to the jury by any means, such as making statements or offers of proof or asking questions in the hearing of the jury.

(d) Plain error. Nothing in this rule precludes taking notice of plain errors affecting substantial rights although they were not brought to the attention of the court.

Federal Rule of Evidence 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible.

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Federal Rule of Evidence 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion or Waste of Time.

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Federal Rule of Evidence 703. Bases of Opinion Testimony by Experts.

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in the evidence.

Federal Rule of Civil Procedure 61. Harmless Error.

No error in either the admission or the exclusion of evidence and no error or defect in any ruling or order or in anything done or omitted by the court or by any of the parties is ground for granting a new trial or for setting aside a verdict or for vacating, modifying or otherwise disturbing a judgment or order, unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

INTERMEDICS' OFFER OF PROOF

[1743]* THE COURT: Be seated. And Mr. Hofer for Defendant, Intermedics, called as a witness Dr. Gambrell and there are certain portions of Dr. Gambrell's testimony that Mr. Hofer wants into the record and before the jury. The Court entertains doubt as to the admissibility of the proffered testimony, therefore, has excluded the jury and now gives you, Mr. Hofer, this opportunity to make a bill or an offer upon that testimony.

MR. HOFER: Thank you, Your Honor, and I wish for the record that it be understood that in this offer of proof, each of these items which I will try to identify separately are being offered separately, and the evidence, therefore, is not to be considered in toto, but each bit of offered evidence must be considered on its own merits, and this Court, having previously ruled that each and every one of those items could not be presented as evidence in this case.

THE COURT: All right.

MR. HOFER: Professor Gambrell's qualifications have been placed before the jury, so I need not repeat them. The first broad [1744] category of evidence relates to his review of the prosecution history of the Rasor-Spickler patent. First, based upon his review, he would explain the inventive concept of the Rasor-Spickler patent. He would explain that the Rasor-Spickler patent covers the concept of a spaced, anchored electrode, and that that electrode has two aspects to it. One is a plurality of anchor means coupled with the second part, being spaced, those plurality of anchors means being spaced from the point of stimulation.

---

* Numbers in brackets refer to the pagination of the Joint Appendix filed in the CAFC.

Second, he would explain why and how this spaced, anchored electrode concept was set forth in the specification of the Rasor-Spickler patent and covered by Claims 1, 2 and 5 at issue in this litigation.

Third, he would review the prosecution history of the Rasor-Spickler patent and discuss and explain the prior art relied upon by the examiner and cited by the examiner and explain the responses made by the applicant to various rejections made by the examiner.

And fourth, he would explain that Claims 1, 2 and 5 are not limited to metal tines, stainless steel tines, piercing tines, pronged, [1745] barbed hooks or penetrating tines.

He would also explain that the number of tines that the claims cover any number of tines, so long as there are two or more. The claims are not limited to anything other than a plurality of anchoring means. He would also explain that the claims are not limited to tines or anchoring means that pierce or penetrate heart tissue.

Number six, he would explain that Claims 1, 2 and 5, the claims of issue, cover Intermedics tined leads at issue in this litigation. In other words, that Intermedics tined leads involved in this litigation infringe 1, 2 and 5 of the Rasor-Spickler patent.

The next item he would also explain that the Medtronic tined leads are covered by Claims 1, 2 and 5, the claims at issue in this litigation; in other words, that Medtronic's tined leads infringe Claims 1, 2 and 5 of the Rasor-Spickler patent and would explain in both instances how the claims cover these devices and why these devices satisfy all of the limitations set forth in those claims.

The next item he would explain why the alleged doctrine of reverse equivalence is not [1746] applicable in this case and, therefore, is not defense available to Medtronic to the charge of infringement of Claims 1, 2 and 5 of the

Rasor-Spickler patent. The next item he would also explain that Claims 1, 2 and 5 covered plastic tines, and the reasons why these claims indeed embrace plastic tines.

The next item, he would discuss the art and explain the art cited during the prosecution of the 864 patent, which was the parent patent, and explain that the claims were allowed because the prior art did not show the combination of a plurality of radiating anchor means coupled with remote attachment from the point of stimulation.

The next item he would explain is that he has reviewed the file history of the reissue application of the Rasor-Spickler patent and would discuss the prosecution history of that reissue application.

As the next item, he would point out that during the prosecution of the reissue application, the applicants brought to the attention of the Patent office a flanged lead and discussed that flanged lead in an amendment that they submitted to the examiner and that the file [1747] history indicates that the examiner, having the benefit of those comments, took no action insofar as the pending claims were concerned; in other words, that the examiner based upon his examination of the claims pending, did not consider flanged leads to be any more relevant than any of the prior art being relied upon by the examiner at that time.

Professor Gambrell would also discuss the fact that all of the claims and the reissue application are considered to be reexamined during the re-examination process, and that this application was allowed by the Court of Appeals in the Patent office, the Board of Appeals in the Patent office.

And lastly with respect to the Rasor-Spickler patents, Professor Gambrell would have pointed out that during the prosecution of the original patent, the Patent office required an election between three inventive concepts;

namely, the intracardiac pacemaker, the electrodes, and the introducer, and that the applicant elected prosecute the electrode.

* * * * *

[1750] And lastly for the record, I just note that in the pre-trial order submitted to this Court by the parties on Medtronic's list of witnesses, they included Donald Banner, a former Commissioner of Patents referred to in Mr. Lynch's opening statement as a witness who will, quote, testify concerning the prosecution of both the Citron and Rasor patents, end of quote.

That concludes my offer of proof, Your Honor.

THE COURT: Yes, sir. Mr. Lynch, do you have any response to make?

[1751] MR. LYNCH: May it please the Court, Your Honor, I believe that the offer of proof quite clearly indicates that it would be usurping the function of the jury and the Court and in this case would constitute what Judge Leonard Hand spoke of as a burdensome impertinence.

MR. HOFER: I will not respond, Your Honor. This is a matter we have, I think, debated off the record, and I know Your Honor has already ruled with respect to this, so I do not wish to burden your Honor's time with rearguing that matter.

THE COURT: Let me just ask you this: Each of you have participated in numerous patent cases; is that correct?

MR. LYNCH: That's correct, Your Honor.

MR. HOFER: That's correct.

THE COURT: During your long and varied experience in patent litigation, how often, if ever, has a witness been used whose expertise is in the law and whose purpose is to give testimony with regard to the intricacies of patent law as applied to patent procedure and ultimately the patentability of products and the [1752] infringement of patents that have been granted? Do we have—

MR. HOFER: In my experience, Your Honor, when we're talking about a jury trial, I am not aware of instances where such testimony has been excluded. In fact, the last case that tried with Mr. Lynch, Mr. Lynch in a jury trial, Mr. Lynch put on a former Commissioner of Patents who was permitted to discuss what happened during the course of the prosecution of the patent involved in suit.

THE COURT: Because he was there, I suppose, which gave him a more immediate knowledge than one who merely reviews the record.

MR. HOFER: No, Your Honor. He had no involvement in that application. Actually, the Commissioner of Patents is really an administrative position and he does not examine them.

THE COURT: Did he testify at such a trial that he has reviewed the claim, he has familiarized himself with the history of the patent application, and through the process of examination by the Patent office, ultimately culminating in a patent and he concludes that the [1753] claims do or do not encompass those things that are in controversy at the time of trial.

MR. HOFER: He was not permitted to give those opinions at this trial. But in Medtronic's trial against Daig, they put on the Commissioner of Patents and he expressed an opinion as to infringement.

MR. LYNCH: That was a hearing before the Court, Your Honor, on a preliminary injunction.

THE COURT: Yes, sir. The Court is going to abide by its ruling and you have your proffer fully perfected in the record.

MR. HOFER: Thank you, Your Honor. I appreciate that.

* * * * *